Claim Listing

1-13. (Canceled).

14. (Previously presented) A method of performing a clinical trial comprising:

randomizing with a processor study participants into a plurality of treatment groups;

performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of said plurality of treatment groups, and administering a placebo to a remainder of said treatment groups;

determining whether each participant in each of said treatment groups is a responder or a non-responder;

performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group; and

analyzing with a processor data from said first phase of testing and from said second phase of testing,

wherein said analyzing comprises determining an effect of active treatment, and

wherein said determining an effect of active treatment is performed in accordance with the formula:

$h = w(p_1 - q_1) + (1-w)(p_2 - q_2)$ wherein h is a value representative of effectiveness of the active treatment, w is a weighting factor, p_1 is a response rate to the administration of active treatment during said first phase, q_1 is a response rate to the administration of placebo during said first phase, p_2 is a response rate to the administration of active treatment during said second phase, and q_2 is a response rate to the administration of placebo during said second phase.

15. (Previously presented) A method of performing a clinical trial comprising:

randomizing with a processor study participants into a plurality of treatment groups;

performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of said plurality of treatment groups, and administering a placebo to a remainder of said treatment groups;

determining whether each participant in each of said treatment groups is a responder or a non-responder;

performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group; and

analyzing with a processor data from said first phase of testing and from said second phase of testing,

wherein said analyzing comprises determining an effect of active treatment, and

wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w\left(\frac{n_{3,1}}{n(1-2a)} - \frac{(n_{1,2}+n_{2,3})}{2na}\right) + (1-w)\left(\frac{n_{2,1}}{n_{2,1}+n_{2,2}} - \frac{n_{1,1}}{n_{1,1}+n_{1,2}}\right),$$

wherein h is a value representative of effectiveness of the treatment, w is a weighting factor, n is the total number of study participants, $n_{1,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to placebo in the second phase, $n_{1,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to placebo in the second phase, $n_{1,3}$ is the number of participants who were responders to placebo in the first phase and were responders to placebo in the second phase, $n_{2,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to treatment in the second phase, $n_{2,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to treatment in the second phase, $n_{2,3}$ is the number of participants who were responders to placebo in the first phase and were responders to treatment in the second phase, $n_{3,1}$ is the number of participants who were responders to treatment in the first phase, and a is a randomization fraction.

16. (Currently amended) The method of claim 14 wherein data from ~~said~~ administering placebo during said second phase to non-responders in said first group is not used

in said determining said ~~placebo~~ response rate to the administration of placebo during said second phase.

17-33. (Canceled).

34. (Previously presented) A method of performing a clinical trial comprising:

performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of a plurality of treatment groups of study participants, and administering a placebo to a remainder of said plurality of treatment groups of study participants, wherein said study participants have been randomized with a processor into said plurality of treatment groups;

determining whether each participant in each of said treatment groups is a responder or a non-responder; and

performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group,

wherein data from said first phase of testing and from said second phase of testing are analyzed with a processor,

wherein said analyzing comprises determining an effect of active treatment, and

wherein said determining an effect of active treatment is performed in accordance with the formula:

$h = w(p_1 - q_1) + (1-w)(p_2 - q_2)$, where h is a value representative of effectiveness of the active treatment, w is a weighting factor, p_1 is a response rate to the administration of active treatment during said first phase, q_1 is a response rate to the administration of placebo during said first phase, p_2 is a response rate to the administration of active treatment during said second phase, and q_2 is a response rate to the administration of placebo during said second phase.

35. (Previously presented) A method of performing a clinical trial comprising:

performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of a plurality of treatment groups of study participants, and administering a placebo to a remainder of said plurality of treatment groups of

study participants, wherein said study participants have been randomized with a processor into said plurality of treatment groups;

determining whether each participant in each of said treatment groups is a responder or a non-responder; and

performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group,

wherein data from said first phase of testing and from said second phase of testing are analyzed with a processor,

wherein said analyzing comprises determining an effect of active treatment, and

wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w\left(\frac{n_{3,1}}{n(1-2a)} - \frac{(n_{1,3}+n_{2,3})}{2na}\right) + (1-w)\left(\frac{n_{2,1}}{n_{2,1}+n_{2,2}} - \frac{n_{1,1}}{n_{1,1}+n_{1,2}}\right)$$, where h is a value representative of effectiveness of the treatment, w is a weighting factor, n is the total number of study participants, $n_{1,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to placebo in the second phase, $n_{1,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to placebo in the second phase, $n_{1,3}$ is the number of participants who were responders to placebo in the first phase and were responders to placebo in the second phase, $n_{2,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to treatment in the second phase, $n_{2,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to treatment in the second phase, $n_{2,3}$ is the number of participants who were responders to placebo in the first phase and were responders to treatment in the second phase, $n_{3,1}$ is the number of participants who were responders to treatment in the first phase, and a is a randomization fraction.

36. (Currently amended) The method of claim 34 wherein data from ~~said~~ administering placebo during said second phase to non-responders in said first group is not used

in said determining said ~~placebo~~ response rate to the administration of placebo during said second phase.